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Prenylflavanoids as a biomarker of beer consumption

Submission date	Recruitment status	[_] Prospectively registered
24/04/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/05/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/05/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Background and study aims
Prenylflavanoids (a group of plant hormones) are mainly found in hops, and therefore, in beer. Thus, the intake of beer might be assessed through its quantity present in the urine. The aim of this study is to assess the usefulness of urinary prenylflavanoids as a biomarker of beer consumption.

Who can participate?
Healthy adults, in the age range 18-35 years, non-smokers, without previous history of heart, liver or kidney disease, disorders with body balance, any other long-lasting diseases, high blood pressure or Dyslipidemia (abnormal cholesterol/fat level in the blood), alcoholism or other toxic abuse.

What does the study involve?
The volunteers were given different doses of beer at dinner in a random order. Male volunteers consumed 330, 660 and 990 ml of beer, and female volunteers consumed 330, 495 and 660 ml of beer. Before each dose, volunteers followed a 4-day wash-out period in which they were requested to avoid consuming any type of hop-based products and beer. Urine sample was collected before each dose.

What are the possible benefits and risks of participating?
There are no risks as long as the exclusion criteria are followed. The study was conducted according to the Declaration of Helsinki of the World Medical Association. The study was explained to subjects through verbal and written instructions, and written informed consent was obtained before participation.

Where is the study run from?
This study involved the Department of Nutrition and Food Science of the University of Barcelona (Barcelona, Spain) and the Department of Internal Medicine, Hospital Clinic, Institut d Investigació Biomèdica August Pi i Sunyer (IDIBAPS), University of Barcelona (Barcelona,Spain).

When is the study starting and how long is it expected to run for?
This study was conducted between March 2011 and October 2011.

Who is funding the study?
This study was supported by the European Foundation for Alcohol Research (ERAB) (Belgium).

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Urinary isoxanthohumol excretion as a biomarker of beer consumption

Study objectives
Hops and beer are a unique source of xanthohumol, isoxanthohumol and 8-prenylnringenin. Therefore, prenylflavanoids, such as isoxanthohumol and their metabolites may be a potent biomarker of beer consumption, thus the intake of beer can be assessed by quantifying isoxanthohumol in urine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of University of Barcelona (Institutional Review Board IRB00003099), 04/07/2011

Study design
Dose-response randomised cross-over clinical trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Beer consumption

Interventions
Male volunteers:
Intervention 1: Administration of 330 mL beer (14.5 g ethanol)
Intervention 2: Administration of 660 mL beer (29 g ethanol)
Intervention 3: Administration of 990 mL beer (43.5 g ethanol)

Female volunteers:
Intervention 1: Administration of 330 mL beer (14.5 g ethanol)
Intervention 2: Administration of 495 mL beer (21.7 g ethanol)
Intervention 3: Administration of 660 mL beer (29 g ethanol)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Concentrations of urinary prenylflavanoids will be determined by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS). These determinations will be carried out in first morning urine samples collected the day before the first intervention and in the subsequent mornings following each intervention. Creatinine adjustment will be used to normalize analyte concentrations in these urine samples.

Key secondary outcome(s))
No secondary outcome measures

Completion date
28/10/2011

Eligibility

Key inclusion criteria
Young healthy volunteers of age 28±3 years, body mass index 22.69±2.69 kg/m2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Previous history of cardiovascular disease (ischemic heart disease criteria - angina, recent or old myocardial infarction, cerebral vascular accident or peripheral vascular disease)
2. Homeostatic disorders
3. Any several chronic diseases
4. Hypertension or dyslipidemia
5. Smoking subjects
6. Alcoholism
7. Other toxic abuse

Date of first enrolment
31/03/2011

Date of final enrolment
28/10/2011

Locations

Countries of recruitment
Spain

Study participating centre
Av. Joan XXII s/n
Barcelona
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Sponsor information

Organisation
Center for Biomedical Research in Pathophysiology of Obesity & Nutrition (Ciber Fisiopatología de la Obesidad Nutrición)(Spain)

ROR
https://ror.org/02s65tk16

Funder(s)

Funder type
Research organisation

Funder Name
Center for Biomedical Research in Pathophysiology of Obesity and Nutrition (CIBERobn) (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes